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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

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3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ET

<b>Office Action Summary</b>	<b>Application No.</b> 10/606,533	<b>Applicant(s)</b> RHODES ET AL.	
	<b>Examiner</b> Jeffrey G. Hoekstra	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-21 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 11, 13, 18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7, 9, 12, 14-17, 19 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Notice of Amendment*

1. In response to the amendment filed on 08/27/2007, amended claim(s) 3, canceled claim(s) 1, 2, and 22-45, and withdrawn claim(s) 8 and 10 is/are acknowledged. The following new and reiterated grounds of rejection are set forth:

### *Election/Restrictions*

2. Applicant's election of Species B, a modular surgical embodiment drawn to claims 3-7, 9, and 11-21, in the reply filed on 08/27/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 8 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/27/2007.

4. Claims 11, 13, 18, and 20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/11/2006.

5. The Examiner notes the elected invention is drawn to Species IV: embodiment drawn to Figures 20-24 and Species B: embodiment drawn to a modular surgical instrument. The claims reading thereon are claims 3-7, 9, 12, 14-17, and 19.

Art Unit: 3736

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

7. The drawings were received on 08/10/2006. These drawings are unacceptable.

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore,

- the “kit” comprising separate “actuator module(s)” and “surgical tool module(s)” of claims 12 and 17,
- the “actuator module” and “discrete tool module” of claim 5,
- the “tool module being free from any structure for moving the slide member in the distal direction” of claim 16, and
- the elongate distance references having a “substantially straight and parallel” unstressed shape” of claims 9 and 21

9. must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

10. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

Art Unit: 3736

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

12. Claim 3 is objected to because of the following informalities: it appears in at least lines 2, 5, and 15 that "the instrument" should apparently read "the surgical instrument". Appropriate correction is required.

13. Claim 3 is objected to because of the following informalities: it appears in lines 6-7 "a slide member having a proximal end and a distal end, a drive surface and a through-slot at the drive surface between the two ends" should apparently read "a slide

Art Unit: 3736

member having a proximal end, a distal end, a drive surface, and a through-slot at the drive surface between the proximal and distal ends". Appropriate correction is required.

14. Claim 3 is objected to because of the following informalities: the positive recitation of "located on the proximal side of the hollow elongate support member" in line 8 appears to lack antecedent basis and may render the claim indefinite. The Examiner notes Applicant may have intended to positively recite "located on a proximal side opposite the distal end of the hollow elongate support member" or the like. Appropriate correction is required.

15. Claim 3 is objected to because of the following informalities: the positive recitation of "a grip portion" in line 9 appears to duplicate the "a grip portion" in line 3 and may render the claim indefinite. The Examiner notes Applicant may have intended to positively recite "a lever grip portion" in line 9, or the like. Appropriate correction is required.

16. Claim 3 is objected to because of the following informalities: the positive recitation of "a grip portion on one side of the pivotal connection and an integral drive portion on the other side of the pivotal connection" in lines 9-11 appears to lack antecedent basis and may render the claim indefinite. The Examiner notes Applicant may have intended to positively recite "a grip portion on one side of the lever and an integral drive portion on an opposite side of the lever" or the like. Appropriate correction is required.

17. Claim 3 is objected to because of the following informalities: it appears in lines 17-18 that "the lever; and wherein" should apparently read "the lever; wherein".

Appropriate correction is required.

18. Claim 3 is objected to because of the following informalities: it appears in lines 19-20 that "the slide member the surgical instrument" should apparently read "the slide member; and the surgical instrument". Appropriate correction is required.

19. Claim 5 is objected to because of the following informalities: it appears in line 12 that "a discrete surgical instrument" should apparently read "a discrete surgical implement". Appropriate correction is required.

20. Claim 12 is objected to because of the following informalities: it appears in line 1 that "the instrument" should apparently read "the surgical instrument". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 3 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

23. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship

Art Unit: 3736

between the lever and the slide member of the surgical instrument. As claimed “the surgical instrument is free of any mechanical connection between the lever and the slide member”; however, the scope of the claim encompassing the essential structural cooperative relationship between the lever and the slide member is indeterminate. It is unclear how the slide member is “capable of being moved reciprocally in a linear proximal-distal direction by pivoting the lever” if no “mechanical connection” exists “between the lever and the slide member”. The Examiner notes Applicant may have intended to positively recite “the surgical instrument is free of any permanent mechanical connection between the lever and the slide member”, “the lever and the slide member are disposed in a removable mechanical connection”, or the like.

24. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the slide member of the tool module and the structure responsible for its movement. As claimed “the tool module” is “free from any structure for moving the slide member in the distal direction”. The scope of the claim encompassing the essential structural cooperative relationship between the slide member and the structure responsible for its movement is indeterminate. It is unclear how the slide member is “capable of reciprocal motion in the proximal and distal directions” if “the tool module” is “free from any structure for moving the slide member in the distal direction”. Moreover as evidenced by Applicant, depending claim 19 claims “a spring in the housing for



Art Unit: 3736

urging the slide member toward the proximal end of the housing" such that the slide member is biased in the proximal direction and will return to a proximal position when effected in the distal direction, presumably to create a reciprocal motion.

***Claim Rejections - 35 USC § 102***

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

26. Claims 3-7, 9, 12, 14-17, 19, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Yoon et al. (US 6,547,798 B1, hereinafter Yoon).

27. For claims, 3, 5, 15, 16, and 19, Yoon discloses a disposable modular surgical instrument (10) having a proximal end (the right end of the instrument as best seen in Figure 1), a distal end (the left end of the instrument as best seen in Figure 1), and comprising an actuator module (the proximal region of the instrument) and a tool module (the distal region of the instrument),

- the actuator module (the proximal region of the instrument) for operating the tool module (column 3 line 16 – column 4 line 42) and comprising a handle (18) and a lever (24);
  - the handle (18) disposed at the proximal end of the instrument (as best seen in Figure 1), the handle including a grip portion (104), and an integral support portion (118), the support portion having proximal and distal ends and a support

Art Unit: 3736

- surface between the proximal and distal ends (as best seen in Figures 8 and 9), the handle being substantially open above the support surface;
- the lever (24) pivotally connected to the handle (column 13 lines 11-34), the lever including a trigger/grip portion (170) on one side of the pivotal connection and an integral drive portion (174) on the other side of the pivotal connection, at least part of the drive portion comprising an integral cam received in the slot in the slide member (column 13 lines 11-34), the trigger portion being longer than the drive portion (as best seen in Figure 1), and the drive portion extending through an opening in the support surface of the handle (as best seen in Figure 1); and
  - the tool module (the distal region of the instrument) being insertable into and removable from the actuator module (column 21 lines 35-45), extending distally therefrom (as best seen in Figure 1), and comprising a removable cartridge assembly (column 21 lines 35-45) including a hollow housing (12), a hollow elongate support member (14), a surgical implement (28 and 30), and a slide member (16);
    - the hollow housing (12) having proximal and distal ends (as best seen in Figure 1), the housing surrounding at least a portion of the slide member (as best seen in Figure 2), and wherein the elongate support member and surgical implement extend outward from the housing (as best seen in Figure 20);
    - the hollow elongate support member (14) being fixed to the distal end of the housing (via mounting holes 56), the hollow elongate support member having a proximal end within the housing and extending outwardly from the housing to a free distal end (as best seen in Figure 20), the free distal end having an opening

Art Unit: 3736

(as best seen in figure 2), and the hollow housing and hollow elongate support member defining an open passageway between them (the space between 12 and 14);

- the slide member (16) having a proximal end and a distal end (as best seen in Figure 2) and a through-slot (165) between the two ends, the through-slot extending in a proximal-distal direction and being located on the proximal side of the hollow elongate support member (as best seen in Figure 2), wherein the slide member is operably connected to at least part of the surgical implement (as best seen in Figure 2) and is capable of reciprocal motion in the proximal-distal direction relative to the housing, and wherein the slide member has a drive surface within the housing (the surface of element 16);
- the surgical implement (28 and 30) having a proximal end connected to the distal end of the slide member (as best seen in Figure 2), an elongate portion extending through the hollow elongate support (as best seen in Figure 2), and a distal end, wherein the surgical implement is capable of reciprocal motion in the proximal-distal direction relative to the hollow elongate support member by pivoting the lever (column 3 line 16 – column 4 line 42), wherein at least part of the surgical implement extends through the hollow elongate support member and out through the opening at the free distal end of the elongate support member (as best seen in Figures 15 and 20), and wherein the surgical implement has a proximal part extending past the proximal end of the hollow elongate support member into the housing (as best seen in Figure 15);

Art Unit: 3736

- a spring (194) to urge the slide member toward the proximal end of the instrument (column 13 line 35 – column 14 line 4); and
- wherein the actuator module and tool module are capable of being assembled and disassembled so that at least one can be reused independent of the other (column 21 lines 35-45), and
- wherein when the actuator module and tool module are assembled the drive portion of the lever engages the drive surface of the slide member so that the slide member and surgical implement can be moved in the distal direction by squeezing the trigger portion of the lever (column 3 line 16 – column 4 line 42).

28. For claim 4, Yoon discloses a disposable modular surgical instrument, wherein the housing has a proximal opening (26) aligned with the slide member, a channel extending distally from the proximal opening (the lumen of element 12), and an entry slot in communication with the channel (the distal opening of the lumen of element 12), wherein the elongate portion of the surgical implement and slide member are capable of being assembled into a subassembly by connecting the elongate portion of the surgical implement to the slide member (column 21 lines 35-45), and wherein the cartridge is capable of being assembled by inserting the subassembly through the proximal opening in the housing, inserting the drive portion of the lever through the entry slot in the housing and into the slot in the slide member, and pushing the elongate portion of the surgical implement through the elongate support member (column 21 lines 35-45).

29. For claim 6, Yoon discloses a disposable modular surgical instrument, wherein the slide member has an elongate slot (165) and the housing has an opening (82)

aligned with the elongate slot so that the actuator module and tool module are capable of being assembled by inserting the drive portion of the lever through the opening in the housing of the tool module and into the elongate slot in the slide member.

30. For claims 7, 9, and 21, Yoon discloses a disposable modular surgical instrument, wherein the surgical implement comprises a pair of elongate substantially flexible distance references (32a,32b) connected at one end to the slide member in the housing and extending out of the free distal end of the elongate support member (as best seen in Figures 20 and 45), the elongate distance references being made of a shape memory material (column 9 lines 4-46) and disposed in an unstressed shape of divergent at the free ends (as best seen in Figures 20 and 45).

31. For claims 12 and 17, Yoon discloses a disposable modular surgical instrument, wherein the instrument comprises a kit including the actuator module and the tool module as separate elements of a kit (column 21 lines 35-45).

32. For claim 14, Yoon discloses a disposable modular surgical instrument, wherein the handle is sized and shaped to support the housing of the tool module and to limit relative proximal-distal movement between the housing of the tool module and the handle (as best seen in Figure 1).

### ***Response to Arguments***

33. Applicant's arguments with respect to claims 3-7, 9, 12, 14-17, 19, and 21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Art Unit: 3736

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736

